



United States
Department of
Agriculture

Animal and
Plant Health
Inspection
Service

Biotechnology
Regulatory
Services

4700 River Road
Riverdale, MD
20737

Dr. Fredy Altpeter
3062 McCarty Hall
PO Box 0110300
University of Florida
Gainesville, FL 32611

Re: Confirmation of the regulatory status of "Highly digestible bahiagrass"

Dear Dr. Altpeter:

Thank you for your letter dated October 19, 2016 inquiring whether your "Highly digestible bahiagrass" (*Paspalum notatum* Fluegge var. *notatum*) is a regulated article under 7 CFR part 340. "Highly digestible bahiagrass" is described as having resistance to ALS-inhibiting herbicides and reduced lignin for improved digestibility and cattle weight gain.

The Plant Protection Act (PPA) of 2000 gives USDA the authority to oversee the detection, control, eradication, suppression, prevention, or retardation of the spread of plant pests or noxious weeds to protect the agriculture, environment, and economy of the United States. The APHIS mission is to protect the health and value of American agriculture and natural resources.

APHIS regulates the importation, interstate movement, and environmental release (field testing) of certain genetically engineered (GE) organisms that are, or have the potential to be, plant pests. Regulations for GE organisms that are or have the potential to be plant pests, under the PPA, are codified at 7 CFR part 340, "Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There Is Reason To Believe Are Plant Pests." Under the provisions of these regulations, a GE organism is deemed a regulated article if it has been genetically engineered using a donor organism, recipient organism, or vector or vector agent that is listed in §340.2 and meets the definition of a plant pest, or that is an unclassified organism and/or an organism whose classification is unknown, or if the Administrator determines that the GE organism is a plant pest or has reason to believe it is a plant pest.

In your October 19, 2016 letter, you describe "Highly digestible bahiagrass" as having resistance to ALS-inhibiting herbicides and reduced lignin conferred by overexpression of a mutated acetolactate synthase gene and RNAi-mediated silencing of the native bahiagrass caffeic acid O-methyltransferase gene, respectively. The introduced coding and non-coding genetic sequences are derived from *Sorghum*

bicolor and *P. notatum*. The introduced genetic sequences do not contain any plant pest sequences, nor were the sequences introduced into the parent bahiagrass with a plant pest vector.

APHIS has reviewed the information in your October 19, 2016 letter and has determined that bahiagrass itself is not a plant pest. Additionally, APHIS agrees that “Highly digestible bahiagrass” as described in your letter does not contain any introduced genetic material from plant pests and no plant pests were used in its development. APHIS also has no reason to believe “Highly digestible bahiagrass” is a plant pest. Therefore, consistent with previous responses to similar letters of inquiry, APHIS does not consider the “Highly digestible bahiagrass” described in your October 19, 2016 letter to be regulated pursuant to 7 CFR part 340.

APHIS is also authorized to protect American agriculture from damage caused by noxious weeds. If APHIS determines that a plant poses a noxious weed risk, APHIS would consider regulating the plant under the noxious weed regulation, 7 CFR part 360. APHIS has the option to regulate plants under 7 CFR part 360 regardless of whether or not they meet the definition of regulated article under 7 CFR part 340. APHIS has determined that *P. notatum* is not currently listed as a Federal noxious weed or listed in any state as a noxious weed.

APHIS has concluded after reviewing the relevant literature that bahiagrass may function as a weed in certain environments. Based on the literature, APHIS also concluded that ALS-resistant bahiagrass may reduce management options where it occurs as a weed, given that ALS-inhibitor herbicides are often used in the control of weedy bahiagrass in agricultural and non-agricultural environments. As part of a comprehensive herbicide resistant management system, APHIS recommends the following:

the adoption of best management practices (BMPs) to delay or mitigate evolution of herbicide resistance in other weeds, to the extent possible. For information and resources on this topic, please see <http://wssa.net/weed/resistance>. In particular, examples of BMPs are outlined by Norsworthy et al. in: Reducing the Risks of Herbicide Resistance: Best Management Practices and Recommendations (Weed Sci. 2012, Special Issue: 31-62). See <http://www.wssajournals.org/doi/pdf/10.1614/WS-D-11-00155.1>.

Please be advised that the importation of these GE bahiagrass lines, like all other bahiagrass, will be subject to APHIS Plant Protection and Quarantine (PPQ), permit and/or quarantine requirements. For further information on importation of bahiagrass, you may contact Shailaja Rabindran at 301-851-2167 or contact the PPQ general number for such inquiries at (877) 770-5990.

Please be advised that "Highly digestible bahiagrass" may still be subject to other regulatory authorities such as FDA or EPA, including obligations with EPA for the registration of a new use herbicide for use on this specific herbicide resistant bahiagrass. Use of an herbicide on bahiagrass not listed on the label may constitute an "off-label" use in violation the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).

Furthermore, should you become aware at any time of any issues or additional information that may affect the Agency's conclusion regarding this inquiry; you must immediately notify the Agency in writing of the nature of the issue. We hope you appreciate our commitment to plant health and support for the responsible stewardship for the introduction of GE plants.

Sincerely,



Michael J. Firko, Ph.D.
APHIS Deputy Administrator
Biotechnology Regulatory Services
Animal and Plant Health Inspection Service
U.S. Department of Agriculture

16 Feb 2017

Date

